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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number: 00167-482001
I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop AF, Commissioner for Patents, Box 1450, Alexandria, VA 22313-1450. Date of Deposit Signature Typed or Printed Name of Person Signing Certificate	Application Number 10/645,962	Filed August 22, 2003
	First Named Inventor David Farrar, et al.	
	Art Unit 3738	Examiner David A. Izquierdo

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

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December 26, 2007

Date December 26, 2007

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required. see below'.

☐ Total of no. forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: David Farrar, et al.	Art Unit	: 3738
Serial No.	: 10/645,962	Examiner	: David A. Izquierdo
Filed	: August 22, 2003	Conf. No.	: 8400
Title	: TISSUE REPAIR AND REPLACEMENT		

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Pursuant to United States Patent and Trademark Office OG Notices: 12 July 2005, New Pre-Appeal Brief Conference Pilot Program, a request for a review of identified matters on appeal is hereby submitted with the Notice of Appeal. Review of these identified matters by a panel of Examiners is requested because the rejections of record are not proper and are without basis, in view of a clear legal or factual deficiency in the rejections. Applicant reserves all rights to address these and additional matters on appeal in any subsequent appeal brief.

The Examiner has rejected claims 1, 8-11, 37 and 49-53 under 35 U.S.C. §102 as being anticipated by Niederauer (WO 01/32072).

Applicant respectfully disagrees with, and hereby asks the panel to review and reverse, this rejection for at least the following reasons.

Both of Applicant's independent claims, claims 1 and 37, require a first component comprising a preformed ceramic scaffold structure and a second component comprising a polymer. The two components have different relative rates of *in vivo* degradation, with the first component having a higher rate of *in vivo* degradation than the second component. As discussed in Applicants' specification, because the first component has a higher rate of *in vivo* degradation than the second component, after implantation of the device the first component degrades *in vivo* leaving a scaffold formed of the second component (i.e., the initial ceramic scaffold degrades, leaving a polymeric scaffold). (See Applicant's specification, page 9, "Polymeric Scaffolds from Polymer/Ceramic Composites.") The resulting polymeric scaffold has pores into which tissue can infiltrate, whereas the device, when initially implanted, does not have sufficient porosity to support tissue ingrowth.

Niederauer discloses an implant that comprises a biodegradable polymer and a biodegradable ceramic. The ceramic is in the form of ceramic particles substantially uniformly distributed through the polymer. (Niederauer, e.g., page 6, paragraph 3, and page 8, second full paragraph.) *In vivo*, or under certain manufacturing conditions, the ceramic particles dissolve more rapidly than the polymer, leaving a porous polymeric structure. (Niederauer, page 10, first paragraph.)

The Examiner alleges that Niederauer discloses a preformed ceramic scaffold structure.

In Applicant's previous response, Applicant noted that there is no mention of a preformed ceramic scaffold in any of the passages cited by the Examiner in the Final Office Action, i.e., page 6, paragraph 5; page 4, paragraph 4; and page 11, paragraph 1. Page 6, paragraph 5 refers to an implant formed by mixing ceramic particles into a polymer. Page 4, paragraph 4 merely discusses biodegradable polymers. Page 11, paragraph 1 discusses bimodal degradation of the ceramic particles and polymer matrix discussed at page 6, paragraph 5.

In response, the Examiner explained in the Advisory Action that the Examiner is equating the polymer and the ceramic particles disclosed in Niederauer with Applicant's preformed ceramic scaffold. Thus, the Examiner equates the entire Niederauer implant with Applicant's preformed ceramic scaffold.

Assuming, for the sake of argument, that the entire Niederauer implant (polymer and dispersed ceramic particles) can properly be construed as a preformed ceramic scaffold, which Applicant does not concede, this interpretation would nonetheless only satisfy the first component recited in Applicant's claim. There is no teaching or suggestion in Niederauer of a second component, comprising a polymer, which has a lower rate of *in vivo* degradation than the first component (according to the Examiner's interpretation, the entire polymer/ceramic implant).

Niederauer cannot anticipate Applicant's claims because if the polymer and ceramic of Niederauer are considered to together constitute a preformed ceramic scaffold then Niederauer lacks Applicant's second component, while if Niederauer's polymer is equated with Applicant's second component Niederauer does not disclose a preformed ceramic scaffold but instead only ceramic particles.

Applicant wishes to note that dependent claim 52 recites that the polymer of the second component "fills interconnecting pores of the ceramic scaffold." If the polymer and ceramic of

Niederauer are together considered to be the preformed ceramic scaffold, as contended by the Examiner, then Niederauer clearly does not disclose a polymer that fills interconnecting pores of this "scaffold." Moreover, there is no suggestion in Niederauer that the implant includes interconnecting pores, or in fact any pores until after the ceramic particles have dissolved.

Therefore, the applicant submits that the rejected claims are patentable over Niederauer.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: December 26, 2007

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